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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,433	10/01/2003	Arpi Matossian-Rogers	2003_1279	5502

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EXAMINER	
JUEDES, AMY E	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 05/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/674,433	MATOSSIAN-ROGERS, ARPI	
	Examiner	Art Unit	
	Amy E. Juedes, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12,14,15 and 17-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-10, 12, 14-15, and 17-30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The examiner of this application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Amy E. Juedes, Group Art Unit 1644, Technology Center 1600.

2. Applicant's reply filed on 3/16/06 is acknowledged. However, upon reconsideration, the restriction requirement issued on 11/17/05 is hereby vacated. The following is a new restriction requirement.

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-10, drawn to an antibody with reactivity against an anti-TCR Vβ antibody; classified in Class 530, subclass 387.2.

II. Claims 1-4 and 6-10, drawn to a ligand with reactivity against an anti-TCR Vβ antibody; classified in Class 530, subclass 350.

III. Claim 12, drawn to a peptide, oligopeptide, or protein that is bound by an antibody with reactivity against anti-TCR Vβ; classified in Class 530, subclass 324.

IV. Claims 14-15, drawn to a peptide, oligopeptide, polypeptide or protein comprising the sequence of ESRP1; classified in Class 530, subclass 300.

V. Claim 17, drawn to a cDNA, RNA, or genomic DNA encoding an antibody with reactivity against an anti-TCR Vβ antibody; classified in Class 536, subclass 23.53.

VI. Claim 17, drawn to a cDNA, RNA, or genomic DNA encoding a ligand with reactivity against an anti-TCR Vβ antibody; classified in Class 536, subclass 23.1.

VII. Claim 17, drawn to a cDNA, RNA, or genomic DNA encoding a peptide, oligopeptide, or protein that is bound by and antibody with reactivity against anti-TCR Vβ; classified in Class 536, subclass 23.5.

VIII. Claims 18-22, drawn to a cDNA, RNA, or genomic DNA encoding a peptide, oligopeptide, polypeptide or protein comprising the sequence of ESRP1, and vectors and host cells comprising said DNA; classified in Class 536, subclass 23.4.

IX. Claims 23-28, drawn to a method for detection of a naturally occurring autoantibody comprising contacting a sample with an antibody with reactivity against an anti-TCR Vβ antibody; classified in Class 435, subclass 7.1.

X. Claims 23-28, drawn to a method for detection of a naturally occurring autoantibody comprising contacting a sample with a ligand with reactivity against an anti-TCR Vβ antibody; classified in Class 435, subclass 7.1.

XI. Claims 30, drawn to a method of treating autoimmune disease with an antibody or fragment thereof which is capable of binding an anti-TCR Vβ antibody; classified in Class 424, subclass 130.1.

XII. Claims 30, drawn to a method of treating cardiovascular disease with an antibody or fragment thereof which is capable of binding an anti-TCR Vβ antibody; classified in Class 424, subclass 131.1.

XIII. Claims 30, drawn to a method of treating cancer with an antibody or fragment thereof which is capable of binding an anti-TCR Vβ antibody; classified in Class 424, subclass 141.1.

Claim 29 link(s) inventions XI-XIII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 29. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35

U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

XIV. Claims 30, drawn to a method of treating autoimmune disease with a peptide that is bound by an antibody which is capable of binding an anti-TCR Vβ antibody; classified in Class 424, subclass 184.1.

XV. Claims 30, drawn to a method of treating cardiovascular disease with a peptide that is bound by an antibody which is capable of binding an anti-TCR Vβ antibody; classified in Class 514, subclass 2.

XVI. Claims 30, drawn to a method of treating cancer with a peptide that is bound by an antibody which is capable of binding an anti-TCR Vβ antibody; classified in Class 514, subclass 25.

Claim 29 link(s) inventions XIV-XVI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 29. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. Groups I-VIII are different products. Nucleic acids, polypeptides, antibodies to the polypeptides, and ligands which bind the polypeptides differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

5. Groups IX-XVI are unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods comprising different method steps, different reagents, resulting in different endpoints. For example, the method of groups XI-XIV requires a subject to be treated, while the methods of groups IX-X do not require a subject or treatment of a subject. Furthermore, the methods of groups XI-XIII require a distinct reagent (an antibody) than the methods of groups XIV-XVI (a peptide). Furthermore, the methods of treating subjects with diverse conditions including cancer, autoimmune disease, and cardiovascular disease are distinct due to the unique etiologies and pathological mechanisms of the disease. For example, treating autoimmune disease would require suppressing an aberrant immune response, while treating cancer would require the opposite outcome.
6.
7. Groups I and X, XIV-XVI are unrelated because the product of groups I is not used or otherwise involved in the process of groups X, XIV-XVI.

8. Groups II and IX, X-XVI are unrelated because the product of groups II is not used or otherwise involved in the process of groups IX, X-XVI.

9. Groups III and IX-X, XI-XIII are unrelated because the product of groups III is not used or otherwise involved in the process of groups IX-X, XI-XIII.

10. Groups IV and IX-XVI are unrelated because the product of groups IV is not used or otherwise involved in the process of groups IX-XVI.

11. Groups V-VIII and IX-XVI are unrelated because the product of groups V is not used or otherwise involved in the process of groups IX-XVI.

12. Groups I and IX, XI-XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP

§ 806.05(h). In the instant case the antibody could be used for affinity purification of antigen.

13. Groups II and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the ligand could be used for affinity purification of antigen

14. Groups III and XIV-XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the peptides could be used to generate specific antibodies.

15. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by their recognized divergent subject matter. Further, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper.

Species Election

16. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

17. If groups XI or XIV are elected, applicant is required to:

A) elect a specific autoimmune disease, such as one of those listed in claim 30.

B) indicate which claims read on the elected species, including any claims subsequently added.

These are distinct species because their etiologies and pathological mechanisms are different.

18. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

19. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

20. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

21. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

22. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

23. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the**

limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light *of In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Amy E. Juedes whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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May 10, 2006

5/12/06
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